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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,526	06/24/2003	William R. Noyes	3222.01US02	1769

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/602,526	NOYES, WILLIAM R.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,13-25,27 and 29-62* is/are pending in the application.

4a) Of the above claim(s) *1-10,13-16 and 39-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-25, 27, 29-38 and 62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response and Amendment after Non-Final Office Action and Applicant's Arguments/Remarks, both filed 11/28/06 is acknowledged.

Claims 1-62 are pending in this action. Claims 17, 27, 29-31 and 33-34 have been amended. New claim 62 has been added. Claims 1-10, 13-16 and 39-61 have been withdrawn. Claims 11, 12, 26 and 28 have been cancelled. Claims 17-25, 27, 29-38 and 62 remain rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17-25, 27, 29-38 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tihon *et al.* (U.S. Pat. No. 5,499,994) in view of Gokcen (U.S. Pat. No. 6,913,744).

The instant invention is drawn to a method of administering a dose of radiation to a patient comprising introducing a biocompatible, biodegradable filler to between a first tissue location and a second tissue location to increase a distance between the first tissue location and the second tissue location, and administering a dose of radioactivity to the second tissue location so that the presence of the filler causes the first tissue location to receive less of the dose of radioactivity compared to the amount of the dose of radioactivity the first tissue location would receive in the absence of the filler, wherein the filler is removed by biodegradation of the filler in the patient.

Tihon *et al.* ('994) teach methods for the treatment of hypertrophy of the prostate gland and methods for dilating an unobstructed portion of the urethra. Tihon *et al.* also teach dilation devices for the urethra for treating benign prostate hyperplasia (see reference column 1, lines 6-13) and Abstract. The methods for treatment are less invasive and less painful than previous methods (col. 1, line 66 – col. 2, line 2).

Tihon *et al.* employs hydrophilic means, which can be any biologically compatible materials such as hydrogels which are capable of expanding slowly when water is absorbed therein (col. 3, lines 52-55).

The hydrophilic particles must be capable of gradually (as opposed to rapidly) expanding. This provides a maximum of comfort to the patient (col. 7, lines 52-58).

Suitable hydrophilic materials taught include polyethylene glycol and hyaluronic acid (col. 7, lines 59-64). The concentration of the hydrophilic material will also affect the rate of expansion. A high concentration of such material will speed the rate or expansion. Also, a high osmolarity, or charge content, will speed the rate of swelling (col. 8, lines 5-11). The hydrophilic material should have a gradual, slow dilation that occurs over a period of at least 30 minutes and preferably over a much longer period (col. 8, lines 33-46). The expandable device can be a expanding bag stent (col. 8, lines 47-65).

This rejection has been maintained and applied to newly added claim 62. Tihon *et al.* teach that a long expansion or swelling period may also be helpful in a longer patency for the resulting dilation. Tihon *et al.* also teach that their device is adapted to remain in the urethra for extended periods of time, such as on the order of seven days to 30 days, the latter being a practical upper limit for retention in the urethra for biocompatible reasons (see col. 8, lines 33-45).

Tihon *et al.* do not teach administering radioactivity to tissue and do not teach a therapeutic agent (*i.e.*, antibiotic).

Gokcen ('744) teaches a method and composition for treating prostate cancer whereby suitable methods of treatment disclosed include administering radiation (see column 1, lines 50-51).

The composition can include an active agent, such as an antibiotic (col. 2, lines 37-40). Antibiotics usually relieve symptoms of acute prostatic infections promptly (col. 7, lines 66-67).

The method of treatment can be carried out by transrectal routes of prostatic injections (col. 12, lines 11-12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the radiation methods and active agents, such as antibiotics, as taught by Gokcen within the treatment methods of Tihon *et al.* One of ordinary skill in that art would be motivated to do so with a reasonable expectation of success because Gokcen teaches that suitable and effective methods for treatment of prostate cancer include administering radiation, dependent on factors such as age of patient and severity of condition and also teach that active agents, such as antibiotics are added to the composition to promptly relieve symptoms of acute prostatic infections. The expected result would be an improved, safe and effective method for treating prostatic conditions in a patient.

Response to Arguments

Applicant's arguments filed 11/28/06 have been fully considered but they are not persuasive.

- **Rejection under 35 U.S.C. §103(a) over Tihon *et al.* (U.S. Pat. No. 5,499,994) in view of Gokcen (U.S. Pat. No. 6,913,744):**

Applicant argued, "The amended claim language makes it el ear that the claimed method involves, among other things, using the filler to increase a distance between the first tissue location and the second tissue location so that the presence of the filler causes the first tissue location to thereby receive less era dose of radioactivity that is applied. The claim was further amended to specify that the filler is removed by biodegradation of the filler in the patient.

Tihon et al. and Gokcen do not disclose among other things, using the filler to increase a distance between the first tissue location and the second tissue location so that the presence of the filler causes the first tissue location to thereby receive less of a dose of radioactivity that is applied. Instead, Tihon et al. teaches dilating a urethra with a swellable material without reference to radiation dosages and Gokcen teaches delivery of specific agents, e.g., collagenase, without reference to how tissue displacement with a filler can be useful in the context of radiation treatment. Accordingly, Tihon et al. and Gokcen do not teach or suggest what is claimed and the artisan reading Tihon et al. and Gokcen would not have any inclination to practice what is claimed.

Moreover, what is claimed is a biocompatible, biodegradable filler wherein the filler is removed by biodegradation of the filler in the patient. Tihon et al. and Gokcen do not teach or suggest this feature in combination with the other claimed features."

Applicant's arguments have been fully considered, but were not found persuasive. The argument that "Tihon and Gokcen do not disclose a filler to increase a distance between a first tissue location and a second tissue location, causing the first tissue location to receive less of a dose of radioactivity" was not persuasive since the prior art clearly teaches methods for employing biodegradable fillers that provide for the gradual or slow expansion and dilation that occurs over lengthy periods of time. The prior art teaches the use of the same biodegradable fillers, i.e, hyaluronic acid as that desired by Applicant and teaches that use of the fillers in the same field of endeavor as the Applicant, i.e., treating hypertrophy of prostate gland. Moreover, with regards to the amended limitation of "the first tissue location receiving less of the dose of radioactivity as compared to the amount of the dose of the radioactivity the first tissue location would receive in the absence of the filler" was not affordable patentable weight because the limitation is relative in nature. The limitation does not set forth any lower or upper ranges with

regards to radioactivity levels administered. The limitation is rather narrative and relative. Nonetheless, the prior art initially recognizes the use of biodegradable fillers, used to provide dilation between tissues.

The argument that "Tihon and Gokcen do not teach a biodegradable filler wherein the filler is removed by biodegradation of the filler in a patient" was not persuasive since the art teaches the same fillers as claimed by Applicant and thus it is expected that the filler would be removed by gradual biodegradation of the filler component.

Applicant's argument that "Tihon teaches dilating a urethra with a swellable material without reference to radiation dosages and Gokcen teaches delivery of specific agents, e.g., collagenase, without reference to how tissue displacement with a filler can be useful in the context of radiation treatment" was not persuasive. Admittedly, while Tihon does not teach application of radiation dosages, the secondary reference of Gokcen was relied upon for the teaching of administering radiation to treat prostatic conditions such as prostate cancer. The secondary reference also teaches inclusion of additional therapeutic agents, such as antibiotics, used to treat prostatic infections. Additionally, it is noted that the instant claims are completely silent with regards to any specific levels, amounts and/or ranges of radiation. The instant claims simply recite a method of administering "a dose" of radiation. This limitation of "a dose" is rather vague and unspecific. It is the position of the Examiner that the claims as currently presented, remain generic enough to read on the teachings of the Tihon and Gokcen combination references.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 1-10, 13-16 and 39-61 drawn to an invention nonelected with traverse in the Response filed 07/20/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604.

The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh
Primary Examiner
Art Unit 1615
February 10, 2007

HUMERA N SHEIKH
PRIMARY EXAMINER
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